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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,925	06/20/2001	Seiichi Araki	MTSU-1001US	7925

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KNOBLE, YOSHIDA & DUNLEAVY
EIGHT PENN CENTER
SUITE 1350, 1628 JOHN F KENNEDY BLVD
PHILADELPHIA, PA 19103

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,925	ARAKI ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *153-182* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *153-182* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed January 9, 2004 has been received and entered into the case. Claims 1 – 152 are canceled; claims 168 – 182 are added; claims 153 – 182 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Objections

Claims objections have been withdrawn due to amendment.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims153 – 182 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While the specification as originally filed describes method for treating diseases caused by bacterial, viral and fungal infection, it does not describe a method for preventing the appearance of a symptom after infection as presently claimed. The specification

neither defines such a symptom nor describes in any way, the claimed method of preventing the appearance of symptoms after infection. This is a new matter rejection.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 153 – 182 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 153, 168 and their dependents are drawn to a method for preventing or remedying infection, however are rendered vague and indefinite for reciting "appearance of a symptom after infection" because this phrase is not adequately defined. Specifically, applicant fails to set forth what is included or excluded from an "appearance of a symptom" after infection. It is unclear if the symptom is a result from the infection, or is merely any "symptom" after any infection.

Claims 153 – 167 are confusing because it is unclear if the phrase "which is effective to prevent appearance of a symptom after infection or remedy a disease caused by infection" in lines 4 – 5 refers to an effective amount of the sugar cane-derived extract or to the effect of the method.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 153 – 158, 160, 163 – 173, 175, 178 – 182 are rejected under 35 U.S.C. 102(a) as being anticipated by Kawai.

Applicant claims a method for preventing appearance of a symptom after infection, or remedying a disease caused by an infection in humans or animals, the method comprising orally administering an effective amount of sugar cane derived extract to a human or animal, wherein the infection is bacterial or viral. The sugar cane extract is a fraction obtained by treating sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses with column chromatography with a fixed carrier. Alternatively, the extract is obtained by passing sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses through a column packed with a synthetic adsorbent as the fixed carrier, eluting with water, methanol, ethanol, or mixtures thereof. The extract is a fraction which absorbs light at a wavelength of 420 nm, separated from other fractions obtained by column chromatography using an ion exchange resin, a cation exchange resin, a strongly acidic, or gel resin. The extract is obtained by extracting bagasse with water, hydrophilic solvent or mixtures thereof wherein the solvent is ethanol, or a mixture of ethanol and water at 60% or less ethanol, and 40% or more water. Finally, the extract is administered as food or animal feed. Applicant additionally claims the method wherein administration is oral, IV, intramuscular, subcutaneous, intra-abdominal, intrarectal, hypoglossal, or instillation; the infection is bacterial, viral or fungal; with the proviso that when administration is oral the infection is fungal.

Kawai teaches methods wherein sugar cane extracts are administered to subjects (human, dogs) (examples 4, 5). Specifically, the sugar cane extracts are obtained by a method wherein sugar cane juice or sugar cane derived molasses is treated with column chromatography packed with a synthetic adsorbent as a fixed carrier, eluted with water, methanol, ethanol or mixes thereof (abstract). The extracts are eluted with a mixed solvent of ethanol and water in a ratio of 50:50 to 60:40 (0017). The material is used in foods, feeds and medicines (0001). Further purification of the sugar cane extract is accomplished with ion exchange resins (0020), cation exchange resins (0021) and gel resins (examples). Kawai teaches that the obtained sugar cane extract can be used in foods, feed, and medicines (0031-0032). Specific examples of such medicines include food and drinks to patients to improve sanitary conditions (0032).

Although Kawai does not teach the method for preventing appearance of symptoms from infection or remedying infectious disease, the method steps are the same. Moreover, by practicing the methods of Kawai, one would inherently be preventing appearance of symptoms after infection. In addition, although Kawai does not specifically teach the extract absorbs light at a wavelength of 420 nm, the methods of obtaining the extracts are the same. As such it would appear that the extract of Kawai would also intrinsically absorb light at the same wavelength. It is noted that if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Applicant argues that Kawai does not teach the humans or animals are infected with a bacteria, virus or fungus, or that the method prevents symptoms of infection from appearing.

However, these arguments fail to persuade because the claims do not require the human or animal to be infected, or that subject be in need of symptom prevention or disease remedying. The claims merely require that a human or animal is administered the sugar cane derived extract. While the reference does not teach the method steps can prevent appearance of symptoms after infection, or remedy an infectious disease, the steps are the same, and therefore must inherently prevent appearance of symptoms after infection. For these reasons and those made above, the claims are rejected.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 153 – 182 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai in view of Saska, Agar, Brewer and Kearny.

Applicant claims a method for preventing appearance of a symptom after infection, or remedying a disease caused by an infection in humans or animals, the method comprising orally administering an effective amount of sugar cane derived extract to a human or animal, wherein the infection is bacterial or viral. The sugar cane extract is a fraction obtained by treating sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses with column chromatography with a fixed carrier. Alternatively, the extract is obtained by passing sugar cane juice, a liquid extracted from sugar cane or sugar cane derived molasses through a column packed with a synthetic adsorbent as the fixed carrier, eluting with water, methanol, ethanol, or mixtures thereof. The extract is a fraction which absorbs light at a wavelength of 420 nm, separated from other fractions obtained by column chromatography using an ion exchange resin, a cation exchange resin, a strongly acidic cation or the sodium or potassium form, or gel resin. The ion exchange is carried out in a pseudo moving bed continuous separation, and the fraction is further treated with electrodialysis. The extract is obtained by extracting bagasse with water, hydrophilic solvent or mixtures thereof wherein the solvent is ethanol, or a mixture of ethanol and water at 60% or less ethanol, and 40% or more water. Finally, the extract is administered as food or animal feed. Applicant additionally claims the method wherein administration is oral, IV, intramuscular, subcutaneous, intra-abdominal, intrarectal, hypoglossal, or instillation; the

infection is bacterial, viral or fungal; with the proviso that when administration is oral the infection is fungal.

Kawai teaches methods wherein sugar cane extracts are administered to subjects (human, dogs) (examples 4, 5). Specifically, the sugar cane extracts are obtained by a method wherein sugar cane juice or sugar cane derived molasses is treated with column chromatography packed with a synthetic adsorbent as a fixed carrier, eluted with water, methanol, ethanol or mixes thereof (abstract). The extracts are eluted with a mixed solvent of ethanol and water in a ratio of 50:50 to 60:40 (0017). The material is used in foods, feeds and medicines (0001). Further purification of the sugar cane extract is accomplished with ion exchange resins (0020), cation exchange resins (0021) and gel resins (examples). Kawai teaches that the obtained sugar cane extract can be used in foods, feed, and medicines (0031-0032). Specific examples of such medicines include food and drinks to patients to improve sanitary conditions (0032).

Although Kawai does not teach the method for preventing appearance of symptoms from infection or remedying infectious disease, the method steps are the same. Moreover, by practicing the methods of Kawai, one would inherently be preventing appearance of symptoms after infection. In addition, although Kawai does not specifically teach the extract absorbs light at a wavelength of 420 nm, the methods of obtaining the extracts are the same. As such it would appear that the extract of Kawai would also intrinsically absorb light at the same wavelength.

Kawai does not teach the method wherein a strongly acidic cation exchange resin is used of the sodium or potassium form, wherein the ion exchange is carried out in a moving bed continuous separation, or wherein the fraction is treated with electrodialysis. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary

skill in the art to obtain extracts of sugar in these claimed methods, because they were routinely practiced in the art. In support, Saska teaches processes wherein sugar juice, or sugar derived molasses is treated with a strong cation exchange resin, in the form or sodium and/or potassium (abstract) and the eluted with water (col.2 line 21-29). Agar teaches methods for pulping plant materials such as bagasse (sugar cane extract), wherein extracts are recovered by treating the material with organic solvents (alcohol) (col.1 line 21-34, col.16 line 15-20), specifically with 60% ethanol and 40% water (col.4 line 24-26,35-50). Brewer teaches known methods for producing extracts of sugarcane using ion exchange, strongly acidic ion exchange resins (col.2 line 12-22), cations resins of the sodium form (col.2 line 33-39), and electrodialysis (col.3 line 8-10). Finally, Kearney teaches typical separation techniques of sugar extracts include ion exchange resins, continuous simulated moving bed systems (col.1 line 30-50). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practices to obtain the sugarcane extract of Kawai as claimed, since they well known procedures, as evidenced by the cited references.

It is noted that if the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper (MPEP 2113). Although the instant claims are drawn to a method, the method merely comprises administering such a product by process.

It is further noted that the instant claims read on eating sugar, since the extracts are obtained by the same methods practiced to obtain sugar (see cited references) and the methods are preventative in nature.

Applicant argues that Kawai does not teach the humans or animals are infected with a bacteria, virus or fungus, or that the method prevents symptoms of infection from appearing.

However, these arguments fail to persuade because the claims do not require the human or animal to be infected, or that subject be in need of symptom prevention or disease remedying. The claims merely require that a human or animal is administered the sugar cane derived extract. While the reference does not teach the method steps can prevent appearance of symptoms after infection, or remedy an infectious disease, the steps are the same, and therefore must inherently prevent appearance of symptoms after infection. For these reasons and those made above, the claims are rejected.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
April 6, 2004.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER